

71 ~~so as to enhance extravasation, implantation, transplantation, invasion and/or migration of said cells in vivo.~~

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 71-73 are in this case. Claim 73 was withdrawn under a restriction requirement as drawn to a non-elected invention. Claims 71-72 have been rejected.

By this amendment, claim 73 has been canceled and claim 71 has been amended.

Attached herewith is a marked up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with marks to show changes made".

Claim Objections

The Examiner has objected to claim for a certain informality which has now been corrected as suggested by the Examiner.

35 USC § 112, First Paragraph Rejections

The Examiner has rejected claims 71-72 under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner's rejections are respectfully traversed. Claim 71 has now been amended.

In particular, the Examiner states that claims 71 and 72 are drawn to a biological preparation comprising cells in suspension. The limitation that the cells of the claimed biological preparation are "cells in suspension" is not supported by the original specification and is thus considered new matter.

The Examiner's attention is respectfully drawn to page 41, lines 6-17 of the specification, reciting that:

Heparanase adherence to cells: Enzyme preparations used were purified recombinant heparanase of approximately 60 kDa expressed in insect cells (see U.S. Pat. application No. 09/071,618, filed May 1, 1998). The adherence of heparanase to cells was performed as follows: cells were plated in either 35 or 90 mm plates with antibiotic free DMEM or F12 media supplemented with 10 % FCS. Following at least 24 hours of incubation in antibiotic-free media, 10 µg/ml of recombinant heparanase from baculovirus were added to cell culture, and incubated for 2 hours at 37 °C. The plates were then washed twice with PBS, harvested by very short trypsinization, washed with PBS, and the pellet was either subjected to activity assay or Western blot analysis, or resuspended and injected into mice. (Emphasis added)

Page 45, lines 1-6 of the specification, stating that:

The injected cells were prepared as follows:

Group 1: B16-F1 cells were grown in DMEM + 10 % FCS (Beit Haemek). Cells were trypsinized, harvested and centrifuged. The pellet was washed with PBS and resuspended in PBS at 2.5×10^5 cells/ml, total of 10^6 in 4 ml for 10 mice. Aliquots were prepared: 2 x 1.5 ml and

1 x 1 ml in 2 ml screw capped tubes. (Emphasis added)

Page 45, lines 15-22 of the specification, stating that:

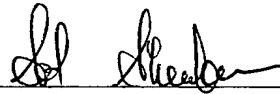
Group 4: Heparanase was adhered to B16-F1 cells: 3×10^6 cells were plated in 8 ml of antibiotic free DMEM supplemented with 10 % FCS. Following 24 hours of incubation, 80 μ g of recombinant heparanase from baculovirus (final concentration of 10 μ g/ml) were added to the cell culture, and incubated for 2 hours at 37 ° C. The plates were then washed twice with PBS, harvested by very short trypsinization, washed with PBS, and resuspended in PBS at 2.5×10^5 cells/ml (total of 10^6 in 4 ml for 10 mice). Aliquots were prepared: 2 x 1.5 ml, 1 x 1 ml in 2 ml screw cap tubes. (Emphasis added)

It is clear from the above recitations, reiterated from the original specification, that the "cells in suspension" of the claimed invention are fully supported by the specification, as the term "resuspended" means that the cells are at present in suspension.

It is hence clear that the recitation "cells in suspension" is fully supported and that the 35 USC § 112, first paragraph, rejection was made in error and should be withdrawn.

In view of the above amendments and remarks it is respectfully submitted that claims 71-72 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Sol Sheinbein', is written over a horizontal line.

Sol Sheinbein
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Date: July 28, 2002.

Encl.:

VERSION WITH MARKINGS TO SHOW CHANGES MADE; and

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In the Claims:

Claim 73 has now been canceled.

Claim 71 has now been amended as follows:

71. (Amended) A biological preparation for use in vivo comprising, ex vivo, cells in suspension and a purified mammalian heparanase enzyme being externally adhered to said cells, thereby increasing a the natural amount of heparanase externally adhered to said cells, so as to enhance extravasation, implantation, transplantation, invasion and/or migration of said cells in vivo.